DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

9/9/97 BFF

544

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-78

August 18, 1997

Mr. M. Lamp, President & General Manager
ADAC HealthCare Information Systems
5 Greenway Plaza
Houston, Texas 77046

Dear Mr. Lamp:

We are writing you because on July 28 through August 1, 1997 FDA Investigator Ronald T. Weber collected information that revealed serious regulatory problems involving cardiac catherization monitoring and recording systems which are manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the CGMP. These violations include, but are not limited to the following:

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures, e.g., all areas of the quality assurance program are not being covered and have not been covered since the beginning of 1993 according to your audit log. These include but are not limited to finished product testing, manufacturing procedures, in-process controls, device master record, installation, failure investigation, QA procedures, and change control.

- Failure to establish and implement an adequate complaint handling program, e.g., records of investigation are not being maintained, service requests and telephone log reports are not reviewed as complaints when the failure fits the definition of a complaint, and there is no formal trending of complaints.

- Failure to establish and implement an adequate failure investigation program, e.g., there are no formal or written procedures maintained.

- Failure to establish and maintain adequate installation and inspection procedures that include documentation of the installation inspection and testing results.

- Failure to establish and implement adequate record keeping procedures, e.g., the production procedures and environmental specifications maintained as a part of the Device Master Record are inadequate because available production instructions are deficient and there are no environmental specifications listed.

You should know that these are serious violations of the law that may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within (15) working days from the date you receive this letter what steps you are taking to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Timothy J. Couzins, Compliance Officer, Food and Drug administration, Florida District, 7200 Lake Ellenor Dr., Suite #120, Orlando, Florida 32809.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the requirements for conformance of your devices with the GMPs and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about the GMP requirements and how they affect your particular device, or about the content of this letter, please contact Tim Couzins at (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director
Florida District